REMARKS

The Office Action Summary Form PTOL-326 indicates that the specification has been objected to by the Examiner. As there is no further explanation of the objection, Applicants have made no amendments to the specification.

With these amendments, claims 1-20 will be pending with this application. Claims 1, 10 and 19 have been amended to specify that the epidural needle is stiff so that it can penetrate and deliver medication to a patient's dura matter. Support for these amendments can be found, at least, in ¶¶ 3, 4, 36 and 39 of the specification. No new matter has been added.

Rejection of Claims 1, 10 and 19 under 35 USC § 102(b)

Claims 1, 10 and 19 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Chu (U.S. Patent No. 5,397,310; hereinafter "Chu").

Amended claim 1 is directed to an epidural needle which comprises a stiff elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough. The distal end has a sharpened tip and the tube has sufficient stiffness to penetrate a patient's tissue and to be placed in a patient's epidural space. A resilient member is permanently mounted within the hub having an opening therethrough defining an inner diameter and disposed in the hub cavity so that the opening is substantially axially aligned and in fluid communication with the open passageway. A clamp selectively movable between an open position is provided wherein the inner diameter of the resilient member is substantially unaffected, and a clamp position wherein the clamp causes a strain to at least a portion of the resilient member thereby reducing, but not occluding, the inner diameter of the opening through at least a portion of the resilient member. When the clamp is in the clamp position, delivery of medicament into a patient's epidural space is permitted.

Amended claim 10 is directed to a combined spinal epidural needle set comprising a stiff epidural needle including an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial hollow bore having an inside diameter therethrough. The distal end is a

sharpened tip suitable for penetrating patient's tissue and entry into the patient's epidural space. A resilient member is provided that has an opening therethrough defining an inner diameter and is disposed in the cavity so that the opening is substantially axially aligned and in fluid communication with the open passageway. A clamp having a releasable latch is disposed about the resilient member, the clamp being selectively movable between an open position wherein the inner diameter of the resilient member is substantially unaffected and a clamp position wherein the clamp causes a strain to the resilient member thereby reducing the inner diameter of the opening through the resilient member. A spinal needle having an outside diameter less than the inside diameter of the hollow tube is disposed within the hollow bore. A practitioner using the epidural needle to position the spinal needle may freely axially move the spinal needle within the hollow bore with respect to the epidural needle and fix a position of the spinal needle relative to the epidural needle by the reduction of the inner diameter opening through the resilient member to a diameter less than the outside diameter of the spinal needle by movement of the clamp to the clamp position. The spinal needle is not occluded allowing delivery of a medicament to a patient's subarachnoid space.

Amended claim 19 is directed to a needle including an elongate tube defining a longitudinal axis having a proximal end, a distal end and an axial bore having an inside diameter therethrough, wherein the distal end is a sharpened tip and the tube has sufficient stiffness to permit entry into a patient's epidural space. The needle further has a hub having a proximal end, a distal end and an open passageway therethrough, the hub being attached to the elongate tube so that the hollow bore of the elongate tube is in fluid communication and substantial axial alignment with the open passageway, the hub further having a cavity disposed therein between the proximal end and the distal end of the hub. A resilient member, distinct from the elongate tube, having an opening, at least in part, therethrough defining an inner diameter is disposed in the cavity so that the opening is substantially aligned and in fluid communication with the open passageway, wherein the resilient member fixedly secured within the cavity and restrained from axial displacement with respect to the hub. The needle further includes a clamp selectively moveable between a first position wherein the resilient member is undeformed, and a second position wherein the resilient member is deformed such that the inner diameter of the opening is

changed through at least a portion of the resilient member, but the inner diameter of the opening is not occluded, thereby allowing delivery of the medicament.

The clamp of each of these claims moves between two discrete positions: one where the resilient member is undeformed; and a second position where the resilient member is deformed enough to compress the inner diameter of the opening is changed to effectively lock the position of a needle within the resilient member without interrupting delivery of medicament to a patient's epidural space or subarachnoid space. Chu fails to teach or suggest a clamp which does not occlude an inner opening when in the clamped position. Chu also fails to provide a stiff elongate tube with a sharpened distal tip suitable for penetrating a patient's epidural space.

The device of Chu has no relationship with a spinal need, epidural needle or spinal/epidural needle set. Chu is directed to "an improved device for closure of a through-passage for use, for example, as a valve for a catheter or as a gripping member for a device such as a guidewire placed in the through-passage or channel." (emphasis added) *(Chu at Col. 1, lines 59-63.)* An object of Chu is to "prevent backflow of blood or other fluid from the proximal end of the catheter." *(Chu at Col. 1, lines 20-21.)* The through-passage of Chu is rotated, which "moves the compression member radially inward to compress the tubing member and reduce and close the opening of the through-passage." (reference numerals omitted; emphasis added) *(Chu at Col. 5, lines 44-47.)* "The conformable interior of the resilient tubing provides a seal about an object, such as a guidewire, if present in the through-passage when the device is in the closed position." *(Chu at Col. 8, lines 65-68.)*

Chu does not teach or suggest a clamp movable between an open and clamped position, where in the clamped position an inner tube is not occluded. In fact, Chu teaches the opposite, that the inner tube is closed upon engaging the clamp. Additionally, Chu does not teach or suggest a sharpened tip on a stiff elongate tube suitable for penetrating a patient's epidural space or subarachnoid space. The only structures discussed by Chu consists of catheters and guidewires. Neither of which are sufficiently stiff to be introduced into a patient's epidural space.

Should the examiner maintain the rejection of the claims as amended, doing so would ignore limitations of the claims. The Federal Circuit has held that language of essential structure

and purpose in a preamble provides "positive limitations to the invention claimed." *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1256-57 (Fed. Cir. 1998) ("To read the claim in light of the specification indiscriminately to cover all types of optical fibers would be divorced from reality. The invention is restricted to those fibers that work as waveguides as defined in the specification.") In the instant case, claims 1 and 19 are directed to an epidural needle and claim 10 is directed to a spinal/epidural needle set. It is improper to read the claim in light of the specification to cover all types of catheter needle structures.

Additionally, the Federal Circuit has expressly held that functional language in the body of a claim cannot be ignored. *See Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 689 (Fed. Cir. 1990); *see also Catalina Marketing International, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 810-811 (Fed. Cir. 2002) ("[b]y virtue of its [the intended use] inclusion in the body of Claim 25, this phrase limits Claim 25"). It is well established that "all claim terms are presumed to have meaning." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004). Should the rejection be maintained, this would fail to give meaning to the term "epidural space" in claims 1, 10 and 19. Doing so would impermissibly read these limitations out of the claims. Furthermore claim 10 includes the limitation permitting delivery of a medicament to a patient's subarachnoid space. Like the claim term "epidural space," these terms cannot be ignored when interpreting the claim.

Therefore, it is respectfully requested that rejection of at least claims 1, 10 and 19 be reconsidered and withdrawn.

Rejection of Claims 1-20 under 35 USC § 103(a)

Claims 1-20 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over McWha et al. (U.S. Patent No. 5,480,389; hereinafter "McWha") in view of Schaffer et al. (U.S. Patent No. 5,429,616; hereinafter "Schaffer")

Arguments against this rejection were filed in an Appeal Brief dated January 10, 2008. These arguments are incorporated herein by reference in their entirety and reproduced below for convenience.

Applicant respectfully asserts that (1) a *prima facie* case of obviousness has not been established; (2) the combination of McWha and Schaffer does not result in the claimed invention, nor does the combination function in the same fashion as the claimed invention; and (3) the proposed modification to Schaffer destroys the intended function of Schaffer.

McWha discloses an apparatus for adjusting the length of a combined spinal epidural needle. With reference to Figure 2, McWha teaches a spinal epidural needle set comprising an epidural needle with a sharpened distal end, a spinal needle located within the epidural needle and an attached hub. McWha describes at column 11, lines 14-67 how to operate the combined spinal epidural needle. The epidural needle is inserted into the patient until the distal point is positioned in an appropriate location within the epidural space. The spinal needle is extended through the epidural needle to puncture the dura mater and come to rest within the subarachnoid space.

Schaffer discloses "an occludable catheter apparatus for blocking the flow of blood from the catheter…" Shaffer, column 1, lines 9-11. The catheter has a clamp mechanism which serves to completely occlude the catheter, thereby preventing the flow of blood through the catheter. "This closure prevents blood from escaping while an infusion set is connected to catheter hub 24." Shaffer, column 5, lines 17-19. As such, the catheter of Shaffer exists in two states, opened or closed.

Schaffer describes at column 5, lines 5-24 how to use the occludable catheter. With reference to Figures 1 and 2, the needle enters a blood vessel. The needle is removed while the catheter is advanced into the lumen of the vessel. The locking members are engaged immediately after the needle is completely withdrawn from the catheter and catheter hub. "This closure prevents blood from escaping while an infusion set is connected to catheter hub." Complete occlusion of the catheter is essential to the function of the Schaffer catheter. Upon removal of the needle from the catheter, capillary action will drive blood from the lumen through the catheter. Complete occlusion of the catheter will prevent this from occurring. However, if the catheter is only partially occluded, thereby reducing the effective radius of the catheter tube, the force driving blood through the catheter will be increased. Thus, a catheter will allow a greater amount of blood to backflow if the catheter tube is partially occluded then if it is not

occluded at all. Therefore, complete occlusion of the catheter is a necessary result of the clamp mechanism.

The office action fails to establish a prima facie case of obviousness. The standards for making an obviousness rejection are summarized in MPEP § 706.02(j) as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. See *In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), viz., (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). Although the analysis need not identify explicit teachings directed to the claimed subject matter, "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385, 1396 (2007). As such, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

A person having ordinary skill and common sense in the art of spinal medication delivery would understand that it is essential to maintain a flow of medication through the spinal needle to

the patient. It would be a poor choice of instruments if there was a risk of occlusion of the spinal needle during medication delivery. The claimed invention is directed toward an epidural needle set comprising a spinal needle located inside an epidural needle. The subject invention allows the clinician to adjust the length of the spinal needle protruding from within the epidural needle. Once the desired length has been established, a clamp mechanism is engaged which locks the spinal needle in place within the epidural needle, thereby fixing the amount of the spinal needle which protrudes from the epidural needle. It is essential that engagement of the clamp does not block, or occlude, the spinal needle. If the spinal needle were occluded by operation of the clamp, medication would not be able to pass through the spinal needle, rendering the epidural needle set of the present invention unsuitable for its intended purpose.

There is no articulated reason with rational underpinning for combining an epidural needle set designed to avoid occlusion, a feature recited in the claims, with an occludable catheter. In rejecting the claims the examiner stated:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the epidermal needle system as taught by McWha with the resilient member and clamp as taught by Schaffer, since such a modification would provide the epidermal needle system with the resilient member and clamp for providing inward collapsing of the side wall portion and to reduce or occlude the apparatus. (emphasis added) May 14, 2007 Office Action, page 4.

The Examiner errs in stating that it would have been obvious that the combination would allow for the reduction of the side wall portion. First of all, it is unclear what "side wall portion" is referred to in the rejection. Assuming that the "side wall portion refers" to the resilient member, the statement that the clamp would "reduce or occlude the apparatus" fails to meet the claimed limitation of "reducing, but not occluding" or "not occluded" in the claims.

An epidural needle set comprised of the combination of McWha and Schaffer would result in an apparatus with diametrically opposite function as that of the subject invention. The purpose of the Schaffer clamp is to completely occlude the catheter, thereby preventing the flow of blood through the catheter. The clamp of the subject invention is designed to reduce the size of the opening within the resilient member, without occluding the catheter. The reduction in size

of the resilient member is necessary to hold the spinal needle in position while simultaneously allowing for the unrestricted flow of liquid through the needle. Therefore, the combination of McWha and Schaffer fails to teach or suggest the claimed invention.

The Examiner has attempted to combine the teachings of McWha with Schaffer to create an epidural needle set with a mechanism for holding the spinal needle at a fixed protrusion from the epidural needle. However, the combination of McWha and Schaffer fails to result in an operative product.

If upon combination, the references "would produce a seemingly inoperative device," then the references teach away from the combination. *Tec Air, Inc. v. Denso Mfg. Mich., Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999), quoting *In re Sponnoble*, 56 C.C.P.A. 823, 405 F.2d 578, 587 (CCPA 1969); see also *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (finding no suggestion to modify a prior art device where the modification would render the device inoperable for its intended purpose). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant . . . [or] if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

The epidural needle set of McWha allows the clinician to extend the spinal needle from within the epidural needle and lock that position by using a pair of concentrically disposed sliding members to which each of the epidural needle and spinal needle are attached. The sliding members must be able to move relative to each other to permit adjustment of the spinal needle. There are no compressive forces applied to the device to cause the spinal needle to be locked in place. The catheter of Schaffer uses a resilient member which can be compressed by the clamp mechanism to completely occlude the needle passageway. Adding these components to McWha would produce an epidural needle set with an occluded needle passageway, and destroy the intended function of McWha, which is to allow adjustment of the spinal needle f. This would result in a product which is not suitable for its intended purpose.

Because the resultant product would be inoperative, there is an implicit teaching away from combining these references. Furthermore, this inoperative resultant product is not the same as the subject invention because the mechanism of the subject invention does not occlude the needle. The lock mechanism of the subject invention is solely used to hold the position of the spinal needle within the epidural needle. Therefore, the combination of McWha with Schaffer fails to obviate the subject invention.

Furthermore, the instant invention is not obvious over McWha in view of Schaffer because the proposed modification to Schaffer renders the Schaffer invention inoperable and the combination was the result of impermissible hindsight.

Applicant respectfully points to M.P.E.P. § 2143.01(V), explaining that "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were prima facie obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged).

The Examiner contends that if the closure has an open position and a closed position that it must have an intermediate position; one in which the catheter is partially occluded. The Examiner further reasons that if there is an intermediate position where the catheter is partially occluded, then it would be obvious to one skilled in the art to stop closure of the clamp at a mid-

point, thereby leaving the catheter in a non-occluded state. There is no suggestion or motivation to modify Shaffer in this manner because it would render the invention of Shaffer unsatisfactory for its intended use; occluding the catheter.

The present facts are analogous to the facts of In re Gordon in that the Office Action's assertion that use of the Shaffer clamp at an intermediary position, hence a reduced diameter of the catheter, would have been obvious. The catheter of Shaffer would not function with this modification as it would not prevent the flow of blood through the catheter. In fact, the restriction would cause an increase in the capillary action which would cause blood to flow through the catheter at an increased rate. The Examiner's modification of Shaffer would in fact render the described catheter to be worse than not engaging the clamp at all. Therefore, it is inappropriate to reject the subject claims based on this modification.

Additionally, the Examiner's contention that the clamp of Schaffer must inherently have an intermediate position is not supported by the disclosure of Schaffer and insufficient to render the present invention obvious. The flaw in the Examiner's reasoning is that a determination of inherency cannot be established by probabilities or possibilities, but it is incumbent upon the Examiner to establish the inevitability of the inherency based upon factual evidence or persuasive scientific reasoning. See *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981), and In re Wilding, 535 F.2d 631 (CCPA 1976). In the present case, the Examiner has not advanced the requisite factual evidence or persuasive scientific reasoning that the use of a clamp mechanism designed to occlude a catheter passageway would work equivalently to a clamp designed to fix the position of a spinal needle within an epidural needle without occluding the spinal needle.

Furthermore, the Examiner's combination of McWha with Schaffer is the result of impermissible hindsight. "Obviousness may not be established using hindsight or in view of the teachings or suggestions of the inventor." *Para-Ordnance Mfg. v. SGS Importers Int'l*, 73 F.3d 1085, 1087 (Fed. Cir. 1995). (citing *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1551-1553 (Fed. Cir. 1983)). "It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992)(citing *In re Gorman*, 933 F.2d 982, 987 (Fed. Cir. 1991)). Here, the Examiner has used the disclosure of the present

invention to suggest an inoperative modification to Schaffer in order to combine it with McWha. Thus, impermissible hindsight was employed to allegedly obviate the present invention.

CONCLUSION

Applicants submit that this response places the pending claims in condition for allowance, and early notice to this effect would be appreciated. A petition for an Extension of Time accompanies this response. If any other fees are due, however, the USPTO is authorized to charge Deposit Account No. 50-3329.

Respectfully submitted,

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